

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

**AXSOME MALTA LTD. and AXSOME
THERAPEUTICS, INC.,**

Plaintiffs,

v.

**ALKEM LABORATORIES LTD.,
AUROBINDO PHARMA USA, INC.,
HETERO USA INC., HETERO LABS
LIMITED UNIT-V, HETERO LABS
LTD., HIKMA PHARMACEUTICALS
USA INC., SANDOZ INC., and UNICHEM
LABORATORIES LTD.,**

Defendants.

Civil Action No. 23-20354 (MCA)(LDW)

(Filed Electronically)

**AXSOME MALTA LTD. and AXSOME
THERAPEUTICS, INC.,**

Plaintiffs,

v.

UNICHEM LABORATORIES LTD.,

Defendant.

Civil Action No. 23-23255 (MCA)(LDW)

(Filed Electronically)

**AXSOME MALTA LTD. and AXSOME
THERAPEUTICS, INC.,**

Plaintiffs,

v.

**HETERO USA INC., HETERO LABS
LIMITED UNIT-V, and HETERO LABS
LTD.,**

Defendants.

Civil Action No. 24-196 (MCA)(LDW)

(Filed Electronically)

**AXSOME MALTA LTD. and AXSOME
THERAPEUTICS, INC.,**

Plaintiffs,

v.

**AUROBINDO PHARMA USA, INC. and
AUROBINDO PHARMA LIMITED,**

Defendants.

**AXSOME MALTA LTD. and AXSOME
THERAPEUTICS, INC.,**

Plaintiffs,

v.

SANDOZ INC.,

Defendant.

**AXSOME MALTA LTD. and AXSOME
THERAPEUTICS, INC.,**

Plaintiffs,

v.

**HETERO USA INC., HETERO LABS
LIMITED UNIT-V, and HETERO LABS
LTD.,**

Defendants.

**AXSOME MALTA LTD. and AXSOME
THERAPEUTICS, INC.,**

Plaintiffs,

v.

**AUROBINDO PHARMA USA, INC. and
AUROBINDO PHARMA LIMITED,**

Defendants.

Civil Action No. 24-309 (MCA)(LDW)
(Filed Electronically)

Civil Action No. 24-860 (MCA)(LDW)
(Filed Electronically)

Civil Action No. 24-3999 (MCA)(LDW)
(Filed Electronically)

Civil Action No. 24-4002 (MCA)(LDW)
(Filed Electronically)

**AXSOME MALTA LTD. and AXSOME
THERAPEUTICS, INC.,**

Plaintiffs,

v.

**ALKEM LABORATORIES LTD.,
HIKMA PHARMACEUTICALS USA
INC., SANDOZ INC., and UNICHEM
LABORATORIES LTD.,**

Defendants.

**Civil Action No. 24-4608 (MCA)(LDW)
(Filed Electronically)**

STIPULATED CONSOLIDATION AND SCHEDULING ORDER

WHEREAS, on September 13, 2023, Plaintiffs Axsome Malta Ltd. and Axsome Therapeutics, Inc. (together, “Axsome” or “Plaintiffs”) filed Civil Action No. 23-20354 in this Judicial District against Defendants Alkem Laboratories Ltd. (“Alkem”), Aurobindo Pharma USA, Inc. (“Aurobindo USA”), Hetero USA Inc., Hetero Labs Limited Unit-V, and Hetero Labs Ltd. (collectively, “Hetero”), Hikma Pharmaceuticals USA Inc. (“Hikma”), Sandoz Inc. (“Sandoz”), and Unichem Laboratories Ltd. (“Unichem”);

WHEREAS, on December 20, 2023, Axsome filed related Civil Action No. 23-23255 in this Judicial District against Unichem;

WHEREAS, on January 11, 2024, Axsome filed related Civil Action No. 24-196 in this Judicial District against Hetero;

WHEREAS, on January 18, 2024, Axsome filed related Civil Action No. 24-309 in this Judicial District against Aurobindo USA and Aurobindo Pharma Limited (together, “Aurobindo,” and collectively with Alkem, Hetero, Hikma, Sandoz, and Unichem, “Defendants”);

WHEREAS, on February 14, 2024, Axsome filed related Civil Action No. 24-860 in this Judicial District against Sandoz;

WHEREAS, on March 19, 2024, Axsome filed related Civil Action No. 24-3999 in this Judicial District against Hetero;

WHEREAS, on March 19, 2024, Axsome filed related Civil Action No. 24-4002 in this Judicial District against Aurobindo;

WHEREAS, on April 5, 2024, Axsome filed related Civil Action No. 24-4608 in this Judicial District against Alkem, Hikma, Sandoz, and Unichem;

WHEREAS, Alkem, Hikma, Sandoz, and Unichem hereby acknowledge their acceptance of service of the complaint in Civil Action No. 24-4608;

WHEREAS, each of the above-captioned actions relate to Axsome's allegations of infringement of patents listed in the FDA's publication entitled "Approved Drug Products with Therapeutics Equivalence Evaluations" (the "Orange Book") for Axsome's Sunosi® (solriamfetol) drug product;

WHEREAS, Axsome and Defendants jointly request that the above-captioned actions be consolidated; and

WHEREAS, Axsome and Defendants submit this Stipulated Consolidation and Scheduling Order following the Court's directive during the April 30, 2024 status teleconference and upon further correspondence with the Court in response to the parties' May 10, 2024 letter (ECF No. 91);

IT IS on this 22nd day of May, 2024,

ORDERED that Civil Action Nos. 23-20354, 23-23255, 24-196, 24-309, 24-860, 24-3999, 24-4002, and 24-4608 (the “Consolidated Action”) are consolidated for all purposes, including discovery, case management, and trial, subject to further order of the Court;

IT IS FURTHER ORDERED that the Clerk’s office shall add Aurobindo Pharma Limited as a defendant on the docket of the Consolidated Action;

IT IS FURTHER ORDERED that all filings in the Consolidated Action shall use the following caption:

AXSOME MALTA LTD. and AXSOME THERAPEUTICS, INC.,

Plaintiffs,

v.

**ALKEM LABORATORIES LTD.,
AUROBINDO PHARMA USA, INC.,
AUROBINDO PHARMA LIMITED,
HETERO USA INC., HETERO LABS
LIMITED UNIT-V, HETERO LABS
LTD., HIKMA PHARMACEUTICALS
USA INC., SANDOZ INC., and UNICHEM
LABORATORIES LTD.,**

Defendants.

**Civil Action No. 23-20354 (MCA)(LDW)
Civil Action No. 23-23255 (MCA)(LDW)
Civil Action No. 24-196 (MCA)(LDW)
Civil Action No. 24-309 (MCA)(LDW)
Civil Action No. 24-860 (MCA)(LDW)
Civil Action No. 24-3999 (MCA)(LDW)
Civil Action No. 24-4002 (MCA)(LDW)
Civil Action No. 24-4608 (MCA)(LDW)
(consolidated)**

(Filed Electronically)

IT IS FURTHER ORDERED that all filings going forward shall be filed in Civil Action No. 23-20354 and that Civil Action Nos. 23-23255, 24-196, 24-309, 24-860, 24-3999, 24-4002, and 24-4608 shall be administratively terminated by the Clerk’s office;

IT IS FURTHER ORDERED that the Consolidated Action shall proceed on the following amended schedule:

Event	Current Date (ECF No. 74)	Amended Date
Plaintiffs file Complaint to bring all currently-issued patents against relevant Defendants	N/A	4/5/2024
Defendants' Answers and Counterclaims to all outstanding Complaints ¹	N/A	4/26/2024
Plaintiffs' Answer to Defendants' Answers and Counterclaims	N/A	5/17/2024
Plaintiffs to Provide Updated Disclosure of Asserted Claims	N/A	5/17/2024
Parties to Exchange Update Rule 26(a)(1) Initial Disclosures	N/A	5/17/2024
Each Defendant Group to Provide Non-Infringement Contentions	4/26/24	6/18/2024
Defendants to Provide Joint Invalidity Contentions	4/26/24	6/18/2024
Plaintiffs to Provide Infringement Contentions to each Defendant Group	9/4/24	10/28/2024
Plaintiffs to Respond to Defendants' Joint Invalidity Contentions	9/4/24	10/28/2024
Parties to Exchange Proposed Claim Terms for Construction	9/18/24	11/8/2024
Parties to Exchange Preliminary Claim Constructions	10/9/24	11/22/2024

¹ Unichem will remain subject to the Court's orders at ECF No. 19 (Civil Action No. 23-23255) and ECF No. 21 (Civil Action No. 24-4608). Axsome's time to answer, move, or otherwise respond to Unichem's responsive pleadings shall be subject to Federal Rule of Civil Procedure 12.

Parties to Exchange Evidence Opposing Claim Constructions	10/29/24	12/13/2024
Joint Claim Construction and Prehearing Statement	11/12/24	12/20/2024
Complete all non-expert <i>Markman</i> discovery	12/11/24	1/10/2025
Opening <i>Markman</i> briefs	1/6/25	1/31/2025
Complete all expert <i>Markman</i> discovery	2/27/25	2/21/2025
Substantial Completion of Document Production	3/24/25	4/18/2025
Responsive <i>Markman</i> briefs	4/11/25	5/9/2025
Parties Jointly Propose <i>Markman</i> hearing schedule	4/28/25	5/16/2025
<i>Markman</i> hearing	TBD	TBD
Deadline for Motions to Amend or to Add Parties	5/12/25	5/30/2025
Close of Fact Discovery	8/25/25	9/19/2025
Parties Exchange Opening Expert Reports on All Issues for which Party Bears Burden of Proof	60 days after the close of fact discovery or the Court's <i>Markman</i> opinion, whichever is later	TBD
Parties Exchange Responsive Expert Reports	75 days after opening expert reports	TBD
Reply Expert Reports	45 days after responding expert reports	TBD
Close of Expert Discovery	45 days after responding expert reports	TBD
Submission of the Parties' Joint Pretrial Order	TBD	TBD
Final Pretrial Conference	TBD	TBD
Trial	TBD	TBD
30 Month Stay Expires	12/17/26	12/17/2026

SO ORDERED.



Hon. Leda Dunn Wettre, U.S.M.J.

SO STIPULATED on May 17, 2024:

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